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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/051,311	01/22/2002	Jan-Michael Peters	0652.2290001	4782

26111 7590 01/26/2005

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WASHINGTON, DC 20005

EXAMINER

FRONDA, CHRISTIAN L

ART UNIT	PAPER NUMBER
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1652

DATE MAILED: 01/26/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Advisory Action	Application No. 10/051,311	Applicant(s) PETERS ET AL.	
	Examiner Christian L Fronda	Art Unit 1652	

--The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

THE REPLY FILED 22 October 2004 FAILS TO PLACE THIS APPLICATION IN CONDITION FOR ALLOWANCE. Therefore, further action by the applicant is required to avoid abandonment of this application. A proper reply to a final rejection under 37 CFR 1.113 may only be either: (1) a timely filed amendment which places the application in condition for allowance; (2) a timely filed Notice of Appeal (with appeal fee); or (3) a timely filed Request for Continued Examination (RCE) in compliance with 37 CFR 1.114.

PERIOD FOR REPLY [check either a) or b)]

- a) ☒ The period for reply expires 3 months from the mailing date of the final rejection.
- b) ☐ The period for reply expires on: (1) the mailing date of this Advisory Action, or (2) the date set forth in the final rejection, whichever is later. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of the final rejection. ONLY CHECK THIS BOX WHEN THE FIRST REPLY WAS FILED WITHIN TWO MONTHS OF THE FINAL REJECTION. See MPEP 706.07(f).

Extensions of time may be obtained under 37 CFR 1.136(a). The date on which the petition under 37 CFR 1.136(a) and the appropriate extension fee have been filed is the date for purposes of determining the period of extension and the corresponding amount of the fee. The appropriate extension fee under 37 CFR 1.17(a) is calculated from: (1) the expiration date of the shortened statutory period for reply originally set in the final Office action; or (2) as set forth in (b) above, if checked. Any reply received by the Office later than three months after the mailing date of the final rejection, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

1. ☐ A Notice of Appeal was filed on _____. Appellant's Brief must be filed within the period set forth in 37 CFR 1.192(a), or any extension thereof (37 CFR 1.191(d)), to avoid dismissal of the appeal.
2. ☒ The proposed amendment(s) will not be entered because:
- (a) ☒ they raise new issues that would require further consideration and/or search (see NOTE below);
 - (b) ☐ they raise the issue of new matter (see Note below);
 - (c) ☐ they are not deemed to place the application in better form for appeal by materially reducing or simplifying the issues for appeal; and/or
 - (d) ☐ they present additional claims without canceling a corresponding number of finally rejected claims.

NOTE: See Continuation Sheets.

3. ☐ Applicant's reply has overcome the following rejection(s): _____.
4. ☐ Newly proposed or amended claim(s) _____ would be allowable if submitted in a separate, timely filed amendment canceling the non-allowable claim(s).
5. ☐ The a) ☐ affidavit, b) ☐ exhibit, or c) ☐ request for reconsideration has been considered but does NOT place the application in condition for allowance because: _____.
6. ☐ The affidavit or exhibit will NOT be considered because it is not directed SOLELY to issues which were newly raised by the Examiner in the final rejection.
7. ☒ For purposes of Appeal, the proposed amendment(s) a) ☒ will not be entered or b) ☐ will be entered and an explanation of how the new or amended claims would be rejected is provided below or appended.

The status of the claim(s) is (or will be) as follows:

Claim(s) allowed: _____.

Claim(s) objected to: 6 and 16.

Claim(s) rejected: 1-5 and 11-15.

Claim(s) withdrawn from consideration: _____.

8. ☐ The drawing correction filed on _____ is a) ☐ approved or b) ☐ disapproved by the Examiner.
9. ☐ Note the attached Information Disclosure Statement(s) (PTO-1449) Paper No(s). _____.
10. ☐ Other: _____

Art Unit: 1652

Advisory Action

Applicants' amendment and request for reconsideration filed 10/22/2004 have been considered but not entered because it raises new issues and requires the institution of new rejections. The amendment has not been entered for the following reasons stated below.

Claims 1 and 11 as amended would be rejected under 35 U.S.C. 112, first paragraph, for lack of enablement for the recited method using any separase substrate peptide comprising the amino acid sequence EXXR, wherein X is any amino acid. The specification provides guidance and working examples for the recited method using peptide substrates of SEQ ID NO: 9, SEQ ID NO: 11, and SEQ ID NO: 12. However, the specification does not provide enablement for using a peptide comprising the amino acid sequence EXXR as a substrate for separase in the recited method. Applicants have not clearly shown that any or all of the amino acids in between "E" and "R" (except for those in SEQ ID NO: 9, 11, and 12) can be used as peptide substrates successfully in the claimed method. Thus, an undue amount of experimentation must be performed to search and screen for any peptide substrate comprising the amino acid sequence EXXR which can be used in the method recited in claims 1 and 11.

Furthermore, claims 1 and 11 as amended would be rejected under 35 U.S.C. 112, first paragraph, for lack of written description for the recited method using any separase substrate peptide comprising the amino acid sequence EXXR, wherein X is any amino acid. The claims are genus claims that encompass any peptide of any amino acid sequence, structure, and biological function comprising the amino acid sequence EXXR. The specification does not disclose additional members of this genus, other than SEQ ID NO: 9, SEQ ID NO: 11, and SEQ ID NO: 12. The disclosed peptides of SEQ ID NO: 9, SEQ ID NO: 11, and SEQ ID NO: 12 are not representative of the claimed genus since other genus members include peptides and proteins with widely differing amino acid sequences, structures, and biological functions. Thus, Applicants have failed to sufficiently describe the claimed invention, in such full, clear, concise, and exact terms that a skilled artisan would recognize Applicants were in possession of the claimed invention.

Since the amendment filed 10/22/2004 has not been entered, all previous rejections and objections made in the Office Action mailed 07/15/2004 are maintained for reasons of record.

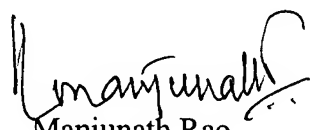
Any inquiry concerning this communication or earlier communications from the examiner should be directed to Christian L Fronda whose telephone number is (571)272-0929. The

Art Unit: 1652

examiner can normally be reached Monday-Friday between 9:00AM - 5:00PM. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ponnathapura N Achutamurthy can be reached on (571)272-0928. The fax phone number for the organization where this application or proceeding is assigned is (571)273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Christian L Fronda
Patent Examiner
Art Unit 1652



Manjunath Rao
Primary Patent Examiner
Art Unit 1652